TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

February, 2005

Trade Name:	InterV® brand CanaliZer Hydrophilic Guide Wire
Common Name:	Guidewire
Classification Name:	Catheter guide wire (per 21 CFR section 870.1330)
Manufacturer's Name:	Medical Device Technologies, Inc. 3600 SW 47th Avenue Gainesville, FL 32608
Corresponding Official:	Kristine Liberacki Quality Manager, MD Technologies, Inc. 3600 Southwest 47th Ave. Gainesvill, FL 32608 Phone: (800) 338-0440 ext, 350 Fax: (352) 33-0662
Predicate Device(s):	Terumo Radifocus Glidewire GT and GOLD, K955801 Terumo Radifocus Guidewire, K924204 Terumo Radifocus Guidewire M, K863138B
Device Description:	The guidewires are constructed from a Nitinol core coated with Tecoflex EG85-A polyurethane to provide a wire with a maximum OD of 0.035" or 0.038". The polyurethane formulation contains $BaSO_4$ for radiopacity. A hydrophilic coating is applied to the distal portion of the guidewire to facilitate wire movement within 0.035" or 0.038" diameter devices. The guidewires are available in lengths of 150, 180 and 260 cm. Two tip shapes are also available, straight and angled. Both tip shapes are provided on wires of standard stiffness, and a stiffer design. The family of guidewires has a CE mark and is in commercial distribution in Europe.

CONFIDENTIAL
This document and the information contained herein may not be reproduced, used or disclosed without written permission from Medical Device Technologies, Inc.

Intended Use:	The CanaliZer Hydrophilic Guide Wire is designed for use in the peripheral vasculature with medical devices requiring a 0.035" or 0.038" outer diameter guidewire. The CanaliZer is not intended for use in the coronary arteries. .
Technological Characteristics:	The guidewires are available in two families, regular and stiff shaft, each in two tip configurations; straight and angled. Each combination is available in 150, 180 and 260 cm lengths.

CONFIDENTIAL
This document and the information contained herein may not be reproduced, used or disclosed without written permission from Medical Device Technologies, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Medical Device Technologies, Inc.
c/o Ms. Kristine Liberacki
Quality Manager
3600 SW 47th Avenue
Gainesville, FL 32608

Re: K050873
CanaliZer Hydrophilic Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: February 18, 2005
Received: April 6, 2005

Dear Ms. Liberacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB 3

INDICATIONS FOR USE

510(k) Number: K050873

Device Name: Medical Device Technologies InterV® brand CanaliZer® Hydrophilic Guide Wire

Indications for Use: The CanaliZer Hydrophilic Guide Wire is designed for use in the peripheral vasculature with medical devices requiring a 0.035" or 0.038" outer diameter guidewire. The CanaliZer is not intended for use in the coronary arteries.

☒ **Prescription Use** (per 21 CFR 801 Subpart D) or ☐ **Over-The-Counter Use** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrine

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050873

CONFIDENTIAL
This document and the information contained herein may not be reproduced, used or disclosed without written permission from Medical Device Technologies, Inc.